

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Offic**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231*ca*

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/480,472

06/06/95

MCDONOUGH

S 213/066

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HM22/0703

EXAMINER

MARSICHEL, A	ART UNIT	PAPER NUMBER
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1631

31

DATE MAILED:

07/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/480,472

Applicant(s)

McDonough et al.

Examiner

Ardin Marschel

Art Unit

1631



- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Mar 9, 2001

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1835 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 39-42, 48-51, 54-56, 67-73, 75-80, 82-93, and 95-172 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 100 is/are allowed.

6) Claim(s) 39-42, 48-51, 54-56, 67-69, 71-73, 75, 76, 78-80, 84-86, 88-93, 95-99, 101-104, 106-122, and 124-169 is/are rejected.

7) Claim(s) 70, 77, 82, 83, 87, 105, 123, and 170-172 is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) ~~One sheet~~, 1 sheet

20) Other: _____

It is noted and acknowledged that the instant application has been revived as granted in Petition decision, mailed 4/25/01.

Applicants' arguments, filed 3/9/01, have been fully considered and they are deemed to be persuasive regarding previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are reiterated from the previous office action, mailed 5/16/00. They constitute the complete set presently being applied to the instant application.

PRIORITY of the Instant claims: It is noted that the earliest priority date for the instant claims directed to specific sequences which are hybridizable to reference sequences given in various instant claims is August 4, 1992. Consideration of the previous parents including 07/855,732 has failed to reveal enabling support for these instant claims. Therefore, the priority date given to the instant claims is August 4, 1992.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 39, 40, 67, 69, 71-73, 75, 76, 78-80, 84-86, 88-91, 95-99, 101-104, 106-122, 124-143, 147-151, 156-162, and 164-167 are rejected under 35 U.S.C. § 102(e) as being anticipated by Kacian et al. (P/N 5,554,516).

This rejection is reiterated and maintained from the previous office action, mailed 5/16/00, and as necessitated by amendment regarding newly examinable claims 91 and 156, which is deemed appropriate due to the below indication of SEQ ID NOS 9 and 10 being disclosed in Kacian et al. Applicants argue that the provisions of newly revised § 103(c) should result in the withdrawal of this rejection. In response, this argument is non-persuasive for two reasons. Firstly, the new provisions of § 103(c) are effective only on applications filed on or after November 29, 1999. The instant application was filed earlier than 11/29/99. Secondly, § 103(c) only prevents rejections under § 103(a) based on obviousness. This section does not prevent rejections under § 102(e) either before, on, or after 11/29/99. Thus, this rejection is maintained and reiterated below.

It is noted that several of the instant sequences are identical to those disclosed in Kacian et al. (P/N 5,554,516) and they are listed as follows:

08/480,472 Kacian et al. (P/N 5,554,516)

SEQ ID NO: 1 14

3 15

4	16
5	17
6	10
8	11
9	12
10	13

These identical sequences of Kacian et al. thus anticipate instant claims directed to such nucleic acids. The open claim language in instant claims 39 and 40 also results in an oligonucleotide comprising instant SEQ ID NO: 22 as being anticipated due to SEQ ID NO: 22 being contained within instant SEQ ID NO: 1 as a 3'-end subsegment. It is also observed that instant SEQ ID NO: 23 is a 3'-end subsegment of instant SEQ ID NO: 6. It is also noted that one embodiment of the kit of instant claim 39 is merely one oligonucleotide such as listed above and thus anticipated by disclosure of a single oligonucleotide. The instant plural oligonucleotide claims such as claim 89 are anticipated because several plural oligonucleotide examples are disclosed in Kacian et al. For example, EXAMPLE 10 starting at column 15 of Kacian et al. includes SEQ ID NOS: 14 and 15 which correspond to instant SEQ ID NOS: 22 as a subsegment of NO: 1 and SEQ ID NO: 3. Other plural oligonucleotide examples of Kacian et al. result in anticipation of such plural oligonucleotide requiring instant claims. DMSO

and glycerol as reaction components are cited in Kacian et al. in Example 9 starting at column 15 which anticipates instant claim 108 with the primer/probe contents that is disclosed in that Example. The molar ratio of instant claim 110 is anticipated in Example 10 in columns 15-16 of Kacian et al.

The above applied reference has several common inventors with the instant application, but not entirely the same inventorship. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. § 102(e). This rejection under 35 U.S.C. § 102(e) might be overcome either by a showing under 37 CFR § 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR § 1.131.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102

of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 39-42, 48-51, 54-56, 67-69, 71-73, 75, 76, 78-80, 84-86, 88-93, 95-99, 101-104, 106-122, and 124-169 are rejected under U.S.C. 103(a) as being unpatentable over Kacian et al. (P/N 5,554,516).

This rejection is reiterated and maintained from the previous office action, mailed 5/16/00, and as necessitated by amendment regarding newly examinable claims 91 and 156, which is deemed appropriate due to the below indication of SEQ ID NOS. 9 and 10 being disclosed in Kacian et al. Applicants argue that the provisions of newly revised § 103(c) should result in the withdrawal of this rejection. In response, this argument is non-persuasive for the following reason. The new provisions of § 103(c) are effective only on applications filed on or after November 29, 1999. The instant application was filed earlier than 11/29/99. Thus, this rejection is maintained and reiterated

below.

Kacian et al. (P/N 5,554,516) at column 4, lines 54-65, describes preferred embodiments wherein promoter-primers contain 3'-end modifications which inhibits or prohibits extension reactions in that direction. Since SEQ ID NO: 14 of Kacian et al. is clearly such a promoter-primer composition as noted in the above 102(e) rejection based on Kacian et al., the above noted column 4 citation is deemed to suggest and motivate additionally a 3' modification thereto as also instantly claimed in claim 50. This issue also applies to instant claims 39 and 40 due to the open claim language therein and as claim 50 depends from claim 40. It is additionally noted that instant SEQ ID NO: 3 is identical to SEQ ID NO: 15 of Kacian et al. It is also noted that kits as required in instant claim 39 is suggested in Kacian et al. at column 5, lines 57-62. The utilization of a mixture of promoter-primers which includes both modified and unmodified 3'-ends is suggested in Kacian et al. at column 5, lines 25-30, which along with the specific sequences noted above regarding Kacian et al. suggests and motivates the practice of instant claim 51. The practice of different 3'-end modifications in a mixture is also suggested and motivated in Kacian et al. at column 9, lines 30-32, as also required in instant claim 54. Labeled oligonucleotides that are complementary or hybridize to target nucleic acids to the above noted sequences is suggested in

Kacian et al. at column 14, lines 42-44 and 64-67, which suggests and motivates these sequences as being labeled, including with acridinium esters as required in instant claims 92 and 93. Example 12 in Kacian et al. at columns 16-17 exemplify RNA target practice which suggests and motivates instant claims 102 and 103. The Preface to the EXAMPLES in Kacian et al. in columns 11-12 indicates the presence or RNaseH or not in various polymerases that are utilized for primer extension which suggests and motivates RNaseH activity as also required in instant claim 104. Example 8 of the reference suggests and motivates additives as also required in instant claim 108.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the promoter-primer of instant SEQ ID NOs: 1 or 22 as noted in the above 102(e) rejection over Kacian et al. wherein a preferred embodiment as given in Kacian et al. at column 4 is a 3'-end modification thus resulting in the practice of instant claim 50 as well as other instant claims as discussed above. Kits of claim 39 are also suggested as given above regarding column 5, lines 57-62, of Kacian et al.

The above applied reference has several common inventors with the instant application. Based on the earlier effective filing U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C.

103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c).

Claims 70, 77, 82, 83, 87, 105, 123, and 170-172 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 100 is allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED

STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

June 29, 2001

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER